

Central Management Committee Decision



PROTECTING PUBLIC HEALTH TOGETHER

CMC Decision on information to be provided in relation to the address of the manufacturer

The CMC decided:

The 'address of the manufacturer' as required in the Essential Requirements on the labels and instruction for use, is the address of the registered place of business of the legally responsible manufacturer and shall include

- street/road,
- number/house/floor,
- postal code
- city
- state/region and
- country

The decision is intended to achieve a common interpretation of the requirement the manufacturer has in relation to provision of his address on the label and instruction for use.

The same details have to be provided for the address of the authorised representative.

Background:

The essential requirements state that the manufacturer has to place his name and the address on the label and on the instruction for use.

In practice wide variations in the information provided has been noted. This could impact adversely on post market surveillance activities.

In order to bring consistency and harmonisation to this issue the CMC decision was taken.

Date of Decision 23rd February 2011

Latest Revision: 7th June 2011